#### PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, March 28, 2000, 10:00 A.M., Massachusetts Department of Public Health, 250 Washington Street, Floor 2, Boston Massachusetts. Present were: Dr. Howard K. Koh (Chairman), Mr. Manthala George, Jr., Ms. Shane Kearney Masaschi, Mr. Albert Sherman, Ms. Janet Slemenda, and Dr. Thomas Sterne. Dr. Clifford Askinazi and Mr. Benjamin Rubin were absent (one vacancy). Also in attendance was Attorney Donna Levin, General Counsel.

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Chairman Koh announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A 1/2.

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The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Mr. Zi, Zhang and Dr. Bruce Cohen, Division of Research and Epidemiology, Bureau of Health Statistics; Dr. Susan Gershman, Director, Massachusetts Cancer Registry; Dr. Jean McGuire, Director, AIDS Bureau, Mr. Andrew Fullen, Director, AIDS Surveillance, and Dr. Alfred DeMaria, Assistant Commissioner, Bureau of Communicable Disease Control; Ms. Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management, Ms. Priscilla Neves, Registered Sanitarian, Division of Food & Drugs; Dr. Paul Dreyer, Director, and Ms. Jean Pontikas, Assistant Director, Division of Health Care Quality; Ms. Joyce James, Director, and Ms. Holly Phelps, Consulting Analyst, Determination of Need Program; and Attorneys Tracy Miller and Kalena Vendetti, Deputy General Counsels, Office of the General Counsel.

# RECORDS OF THE PUBLIC HEALTH COUNCIL MEETINGS OF DECEMBER 28, 1999 AND JANUARY 25, 2000:

Records of the Public Health Council meetings of December 28, 1999 and January 25, 2000, were presented to the Council. After consideration, upon motion made and duly seconded, it was voted (unanimously): That records of the Public Health Council Meeting of December 28, 1999 and January 25, 2000, copies of which had been sent to the Council Members for their prior consideration, be approved, in accordance with Massachusetts General Laws, Chapter 30A, Section 11A ½.

# **PERSONNEL ACTIONS:**

In a memorandum dated March 7, 2000, Dr. Howard Koh, Commissioner, Department of Public Health, recommended approval of the appointment of Philip Dould to Administrator VIII, Chief Operating Officer, Massachusetts Hospital School. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Commissioner of Public Health, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointment of Philip Dould to Administrator VIII, Chief Operating Officer, Massachusetts Hospital School, be approved.

In a memorandum, dated March 7, 2000, Dr. Howard Koh, Commissioner, Department of Public Health, recommended approval of the appointment of Lisa Levine to Program Manager VII, Director, Maternal, Child and Family Health. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Commissioner of Public Health, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointment of Lisa Levine to Program Manager VII, Director, Maternal, Child and Family Health, be approved.

In letters dated March 2, 2000, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of the appointments and reappointments to the various medical staffs of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the various medical staffs of Tewksbury Hospital be approved for a period of two years beginning March 1, 2000 to March 1, 2002:

<u>APPOINTMENTS</u>	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Xiangyang Li, M.D.	Provisional Affiliate Psychiatry	160730
Dominic Maxwell, M.D.	Provisional Affiliate Psychiatry	152901
Katherine Miura, M.D.	Provisional Affiliate Psychiatry	81163
Renee Snow, M.D.	Provisional Affiliate Psychiatry	158443
Robert Tabakin, M.D.	Provisional Affiliate Psychiatry	153040
Sanjay Kamath, M.D.	Provisional Consultant Radiology	81929
Concetta Williams, DPM	Provisional Consultant	2133

## **Podiatry**

REAPPOINTMENTS	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Elissa Ely, M.D.	Active/Psychiatry	71620
Michael Murray, M.D.	Active/Internal Medicine	150381
Linda E. Hutton, Psy.D.	Allied Staff/Psychology	6401

In a letter dated March 14, 2000, Blake Molleur, Executive Director, Western Massachusetts Hospital, Westfield, recommended approval of the reappointment of a physician (Philip Perry, D.M.D., M.D.) to the consultant medical staff of Western Massachusetts Hospital. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Western Massachusetts Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the reappointment to the consultant medical staff of Western Massachusetts Hospital be approved as follows:

REAPPOINTMENT	STATUS/SPECIALTY	MEDICAL LICENSE NO.	
Philip Perry, D.M.D., M.D.	Consultant/Oral Surgery	17927	

In a letter dated March 13, 2000, Robert D. Wakefield, Jr., Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of the appointments and reappointments to the medical and allied staffs of Lemuel Shattuck Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the medical and allied medical staffs of Lemuel Shattuck Hospital be approved as follows:

PHYSICIAN APPOINTMENTS	STATUS/SPECIALTY	MEDICAL LICENSE NO.	
Carole Johnson, M.D.	Consultant/Psychiatry	156599	
Paul Marino, D.M.D.	Consultant/Dentistry	564204	
Scott Shikora, M.D.	Consultant/Surgery	57931	

# PHYSICIAN REAPPOINTMENTS

# STATUS/SPECIALTY

# MEDICAL LICENSE NO.

Peter Grubel, M.D. Consultant/Internal Medicine 158060

Carl Kramer M.D. Active/Neurology 51314

# ALLIED HEALTH PROFESSIONALS – APPOINTMENTS

# <u>SPECIALTY</u> <u>MEDICAL LICENSE NO.</u>

Margaret Ackerman, N.P.	Med/Surg	143431
Julie Banks, A.P.R.N.	HIV	206932
Sally Guy, C.N.S.	Psychiatry	161055
Wm. Levine, F.N.P.	Internal Medicine	216071

# ALLIED HEALTH PROFESSIONALS REAPPOINTMENTS

<u>SPECIALTY</u> <u>MEDICAL LICENSE NO.</u>

Mary Connolly, PA-C Orthopedics 36 Robert Jampel, Ph.D. Psychologist 1634

# **PRESENTATIONS:**

## "ADVANCE DATA BIRTHS 1998"

Dr. Bruce Cohen, Director, Division of Research and Epidemiology, Bureau of Health Statistics, Research & Evaluation made introductory remarks. Mr. Zi Zhang, M.P.H., made the slide presentation to the Council on "Advance Data Births 1998". Statistics from the presentation and executive summary follow:

## **Highlights:**

- In 1998, 81,406 infants were born to women residing in Massachusetts, a 12% increase in the number of births since 1980, but a 12% decrease since 1990. In 1998, 75.9% of Massachusetts births were to white non-Hispanic women, 10.6% to Hispanic women, 6.8% to black non-Hispanic women and 4.6% to Asian women.
- The majority of births were to women over age 30 years. The birth rate among teenagers (ages 15-19) in 1998 remained almost the same as that of 1996 and 1997, while it declined for women in their 20s. The fastest growing age-specific birth rates in the 1990s were for women ages 40 years and above.
- The infant mortality rate (IMR) was 5.1 per 1,000 live births in 1998, representing a 4% decrease from 5.3 per 1,000 in 1997. Black non-Hispanic mothers continue to have the highest IMR 10.6 deaths per 1,000 live births, down 9% from 1997. The IMR was 4.6% deaths per 1,000 live births for white non-Hispanics, a 4% decrease from the 1997 rate. The IMR for Hispanics was unchanged from 1997: 6.7 per 1,000 live births. These patterns should be monitored to see whether they represent trends or merely year-to-year fluctuations.
- Although it is difficult to examine trends in adequacy of prenatal care due to changes in data recorded on the birth certificate and calculation adjustments of the Kessner Index, women in some of the larger, urban communities such as Lawrence, Brockton, Springfield, Lowell and Worcester had much lower rates of adequate prenatal care services than the statewide average. (For a women to be included in the "adequate" prenatal care category, she must of begun prenatal care during her first three months of pregnancy and have received at least nine prenatal visits assuming a full term delivery).
- The Cesarean section delivery rate among Massachusetts residents has declined from 22.4% of live births in 1990 to 20.9% in 1998. Furthermore, 32.7% of women with a previous Cesarean section had a vaginal birth after Cesarean section delivery (VBAC), up from 22.3% in 1990.
- Many women smokers stopped smoking or decreased their daily consumption of cigarettes during pregnancy. Among women who smoked prior to becoming pregnant, 40.3% reportedly quit, 27.3% decreased the amount they smoked, 31.8% smoked at the same level, and fewer than 1% increased their smoking.
- In 1998, 11.2% of women who gave birth had less than a high school education; 27.0% had a high school diploma or GED; 25.0% had some college education; and 36.8% had a least a college degree. Women with more education were more likely to receive adequate prenatal care; more likely to breastfeed; and more likely to have multiple births. They were less likely to smoke during pregnancy and less likely to receive publicly financed prenatal care.
- Massachusetts's perinatal health indicators were generally better than those for the U.S. as a whole in 1998. The IMR was 29% lower; the low birth weight (LBW) rate was 9% lower; the teen birth rate was 44% lower; and use of prenatal care in the first trimester was 2% higher than the U.S.

rates.

- In 1998, 55.4 births occurred for every 1,000 Massachusetts women ages 15-44 years. This represents an 11% decrease since 1990. The Massachusetts birth rate was 16% below the U.S. rate of 65.6 births per 1,000 women ages 15-44 years.
- There were 28.6 live births for every 1,000 women ages 15-19 years, a 19% decrease since 1990. This rate was 44% below the national teen birth rate of 51.1 per 1,000 women ages 15-19.
- The age-specific birth rates were highest for 30-34 years old and 25-29 years old mothers at 102.8 and 81.9 births per 1,000 women, respectively. The birth rates for women ages 30 years and over increased in 1998, as they have throughout the 1990s. The age groups with the largest increases in birth rates since 1990 were 45-49 years (62.5%) and 40-44 years (44.9%). Continuing the trend that was first observed in 1996, there were more births to women ages 30 years and over than under age 30 years.

## **INFANT MORTALITY RATES (IMR)**

- In 1998, 414 infant deaths occurred among Massachusetts residents, 11 fewer than the number of infant deaths in 1997. The 1998 IMR was 5.1 deaths per 1,000 live births. This rate was 29% below the 1998 U.S. preliminary rate of 7.2% deaths per 1,000 live births.
- Between 1980 and 1998, the infant mortality rate decreased by 50% for infants born to black and white women. Infants born to black non-Hispanic mothers continue to have the highest IMR, 10.6% per 1,000 live births. This represents a 9% decrease from the 1997 rate of 11.7, but more than double the IMR for white non-Hispanic mothers (4.6). The 1998 IMR for Hispanics was unchanged from 1997 (6.7 per 1,000 live births), 7% lower than the 1995 rate. Asian mothers have the lowest infant mortality rate, 2.7 per 1,000 live births, compared to the other race/ethnicity groups. (Caution should be used when interpreting this rate since it is based on only 10 deaths).
- Among white non-Hispanic mothers, the neonatal mortality rate (deaths to infants less than 28 days old) decreased 5% from 1997 (3.5 per 1,000 live births in 1998 compared to 3.7% in 1997). During this same time period, the neonatal mortality rate increased by 6% among black non-Hispanic mothers (from 8.0 in 1997 to 8.5 in 1998) and decreased by 4% among Hispanic mothers (from 5.2 in 1997 to 5.0 in 1998). The overall post neonatal mortality rate, representing the number of deaths to infants between 28 and 364 days old, was 1.2 in 1998 and 1.3 in 1997. The post neonatal mortality rate among infants of white non-Hispanic mothers was the same in 1998 as in 1997, 1.1 deaths per 1,000 live births. During the same period, the rates decreased by 41% among infants of black non-Hispanic mothers (from 3.7 in 1997 to 2.2 in 1998), and increased slightly among infants of Hispanic mothers (from 1.5 in 1997 to 1.7 in 1998). The number of post neonatal deaths among Asians remained the same in 1998 as 1997 (3 deaths).

- Among the 30 largest communities in Massachusetts, only one had an infant mortality rate in excess of 10 deaths per 1,000 live births in 1998, compared to 4 communities in 1997, 2 in 1996 and none in 1995. In 1998, the infant mortality rates were highest in Chicopee, 11.4 deaths per 1,000 live births (7 deaths) and Brockton, 9.6 (14 deaths). Because of the relatively small number of infant deaths, year-to-year fluctuations in infant mortality rates for individual communities should be interpreted with caution: none of the 30 largest communities had an average infant mortality rate in excess of 10 deaths per 1,000 live births for the period of 1996 to 1998. Two Massachusetts communities had more than 20 infant deaths in 1998: Boston (46 infant deaths, an IMR of 5.8 compared to 8.4 in 1997) and Springfield (21 deaths, an IMR of 8.9 compared to 9.9 in 1997).
- The leading causes of infant death were conditions arising in the perinatal period (234 deaths) and congenital anomalies (78 deaths). Other causes of infant death include sudden infant death syndrome (SIDS) (22 deaths), disease of the respiratory system (11 deaths), "other diseases of nervous system and sense organs" (6 deaths), and homicide (2 deaths). There were 8 fewer deaths from SIDS in 1998 than there were in 1997.

# Low Birthweight and Prematurity

- In 1998, 6.9% (5,655) of infants born to Massachusetts women were low birthweight (less than 2500 grams or 5.5 pounds). This rate was approximately the same as in 1997 (7.0%) in Massachusetts, and was 9.2% below the national figure of 7.5%.
- The proportion of low birthweight infants varied by mother's race and ethnicity. Black non-Hispanic women had the highest proportion of low birthweight infants (11.8%); Hispanic mothers delivered 7.8% low birthweight infants; Asian mothers 7.5% low birthweight infants; white non-Hispanic mothers delivered 6.3% low birthweight infants. The Massachusetts low birthweight rate for black non-Hispanic women (11.8%) was lower than the 1998 U.S. preliminary rate for all black women (13.0%). The rate of low birthweight for Massachusetts Hispanic women (7.8%) was higher than the corresponding preliminary U.S. rate of 6.4%. This may be due to differences in the composition of the Hispanic population in Massachusetts and the nation as a whole. In Massachusetts, the Hispanic population is composed mainly of people who identify their ethnicity as Puerto Rican, Dominican, and Central American. The U.S. Hispanic population has a much greater percentage of people of Mexican and Cuban descent who have relatively low rates of low birthweight. The Massachusetts low birthweight rate for Puerto Ricans, 9.1% in 1998, was lower than the U.S. Puerto Rican low birthweight rate of 9.4% in 1997.
- In 1998, 7.5% (6,117) of infants born to Massachusetts resident women were preterm (premature), born before the 37<sup>th</sup> week of pregnancy; and 91.8% of infants were born at normal gestational age completion of the 37<sup>th</sup> to 42<sup>nd</sup> week of pregnancy.

#### **Adequacy of Prenatal Care**

- In 1998, 79.8% of women received adequate prenatal care. Adequacy of prenatal care, like infant mortality, varied among racial and ethnic groups. White non-Hispanic women had the highest percentage of adequate prenatal care: 83.6% The percentage of black non-Hispanic women receiving adequate prenatal care was 67.9%, and the percentage of Hispanic women was 66.9%. The percentage of all Asian women with adequate prenatal care was 72.2%. Cambodian women, however, had the lowest percentage of adequate prenatal care, 44.7%.
- Adequacy of prenatal care also varied among the 30 largest Massachusetts communities. At least 85% of mothers in Arlington, Brookline, Framingham, Newton, Quincy, and Weymouth received adequate prenatal care. In contrast, fewer than 70% of mothers received adequate prenatal care in five communities: Lawrence, 58.2%; Lowell, 59.9%; Springfield, 64.7%; Worcester, 67.5%; and Brockton, 66.6%.
- Women whose prenatal care was publicly financed were less likely to receive adequate prenatal care in all race-ethnicity groups. For example, only 59.3% of black non-Hispanic women whose prenatal care was publicly financed received adequate prenatal care, while 80.3% of black non-Hispanic women with private insurance received adequate prenatal care.
- Another measure of access to prenatal care is the percentage of women who receive prenatal care
  in the first trimester of their pregnancy. A higher percentage of Massachusetts women received
  prenatal care in the first trimester compared to the U.S. as a whole: 84.3% in Massachusetts versus
  82.8% nationwide.

#### **Cesarean Sections**

- In 1998, Cesarean section was the method of delivery for 21.0% of the births in Massachusetts maternity care facilities regardless of the mother's state of residence (20.9% for Massachusetts resident mothers), down from 22.5% of the 1990 births. (Calculations are based on births with known method of delivery.) Facilities with low rates of Cesarean section deliveries were: Nantucket Cottage Hospital (11.0%, 8 Cesarean section deliveries performed); Tobey Hospital 13.2%, 53 Cesarean section deliveries performed); and Heywood Memorial Hospital (14.6%, 75 Cesarean section deliveries performed). Seven hospitals had Cesarean section delivery rates of 25% or more (Beth Israel Deaconess Medical Center, Boston Regional Medical Center, Fairview Hospital, Morton Hospital, North Adams Regional Hospital, Quincy Hospital and St. Elizabeth's Medical Center of Boston). And, for the fifth consecutive year, there were no hospitals that reported Cesarean section as the method of delivery for 30% or more of its births.
- In 1998, 32.7% (2,823) of women with a previous Cesarean section, had a vaginal birth after Cesarean delivery (VBAC). The rate of VBACs has increased since 1989 (21.0%).

Ms. Sally Fogerty, Assistant Commissioner, Bureau of Family and Community Health, made brief comments..."I would like to say that our statistics look wonderful. We have many programs. However, I think that what we can use this data for is to assure that we are targeting our resources appropriately. What I would like to do now is introduce Zola Feldman, Executive Director, Great Brook Valley Community Health Center. We have been working with the Worcester community and have learned that in order to really continue to make improvements we need to work closely with the community. And it's the community that is going to reduce disparities. Zola has been working on a special initiative. I'm going to let her share with you how they utilized the data, what it meant, and the program they have developed."

Ms. Zola Feldman, said in part, "With your support we were able to do two things. (1) do analysis on three year moving averages; and then also plot the deaths for a number of years by census tracks. By doing that we were able to demonstrate and be successful in getting Healthy Start planning grants and federal grants....What is most significant is that now we are able to plot the same data with socioeconomic data with smoking prevalence, with injuries for infants up to two years of age, etc. I want to acknowledge the partnership that we have created and I look forward to continuing to work with DPH...."

Chairman Koh added, "Part of the goal of presentations such as today's is to share information statewide so the communities can target efforts to high risk populations."

John Auerbach, Executive Director, Boston Public Health Commission, City Health Department presented statistics for Boston: "The 1998 infant mortality rate in Boston fell to 6.3 per 1,000 live births from the 1997 rate of 8.4. There was a reporting delay of 4 deaths. But translated into the number of of infant deaths, the decline in the rate from 1997 to 1998 meant that 16 fewer babies died in 1998 compared to 1997. That was a significant drop in Boston from 66 deaths to 50 deaths. The rate dropped for both white and black infants, with a sharper drop among whites, a 58 percent drop, versus a 19 percent drop. This has led to the lowest white infant mortality rate in Boston's history, and the second lowest black infant mortality rate in the 1990s. Yet because the drop was greater among whites than blacks, there was actually an increase in the gap between white and black infant mortality in Boston; an area of some concern. The rate for Hispanic babies increased somewhat in 1998, although because the numbers were so small, this may not be a change that is statistically significant. The percentage of low and very low birthweight births both decreased in 1998. And this is a hopeful sign, since these percentages have been relatively stable since the early 1990s. A possible reason for the decline is the decline in both rate and number of multiple births from 1997 to 1998, and a relatively stable multiple birth trend over several years. This, I would note, is different than the trend that was presented on the state as a whole. It may also be a reflection of specific activities that have occurred within the city, many of them with Massachusetts Department of Health support, which have targeted low birth weight. This chart shows that the percentage was lower in 1998 than any other year in the previous decade."

Mr. Auerbach continued, "...Much was relatively unchanged when compared to 1997. And that included women who have smoked during pregnancy and the age distribution of mothers giving birth.

But when looked at over time, there were a number of positive trends, which were observed in the late 1990s when compared with the early 1990s in a few different areas. The percentage of women who smoked during pregnancy dropped from 17 percent at the start of the 1990s to 8 percent in 1997. Adolescent birth rates also dropped from 49.5 to 38.2. What are some the possible reasons for the drop in infant mortality, and some of the other promising indicators, like the decrease in low and very low birthweight babies? One possible reason for the drop is a very significant effort to improve home visiting services in the city. In Boston alone, over 3 million dollars is spent every year in city money on home visiting. In addition to the city money, state and federal funds have supplemented the home visiting efforts. An indication of the emphasis on home visiting is the development of the First Link program, which was initiated by the City Health Department in partnership with the State Health Department. The goal of the First Link program was to ensure that there was a coordinated plan to provide home visits to every baby that was born in the city. We were greatly appreciative of the support that we received from the state in that effort. There also had been in 1998, an effort to strengthen the city's efforts with regard to tobacco control, AIDS, domestic violence prevention. All of which may have contributed to the health of women who were having babies. More recently, we have worked with the state to develop a new strategy of focusing on women's health more broadly, rather than just on prenatal and infant health. This has included a focus on supporting comprehensive health services at community health centers, which we attribute to the increase in the availability of adequate prenatal care. It's also included breast and cervical cancer effort expansions. We received a Reach grant from the federal government this year that allows us to focus in particular on disparities between black women and white women in the city. We have expanded AIDS and substance abuse efforts that target women. And there are several new domestic violence initiatives."

In closing, Mr. Auerbach said, "I'd like to say that we, as a City Health Department, appreciate the partnership that we have had with the State Health Department, the community health centers, and other community providers to address the issues of women's health and infant health. Clearly, the evidence is that through a coordinated public health response, we can make effective inroads in terms of addressing infant mortality."

Dr. Koh added, "You have just heard a very rich series of presentations at the statewide level, from the community, from Worcester, from Boston....First of all, you have seen the importance of statistics and surveillance. It's a concept I think the general public often does not appreciate. But monitoring these trends over time is very important. It gives us a snapshot of what public health looks like in our state, compared to the rest of the country. We have seen much good news today in some of the lowest infant mortality rates ever recorded in Boston and statewide. We have seen how this data prompts people at the community level to target efforts to high risk populations and that's a public health success. We have seen some very dramatic positive trends in smoking rates among pregnant moms, and that's a commitment to building a smoke free generation. That's something that we are all very proud of. I'm particularly proud of the detailed data that you have seen with respect to racial/ethnic groups, because our society is getting so diverse, and part of our public health mission is to help all people reach their full potential for health."

#### No Vote/Information Only

#### "SELECTED CANCERS IN MASSACHUSETTS MEN - 1982-1996"

Dr. Susan Gershman, Director, Massachusetts Cancer Registry of the Department of Public Health presented a report "Selected Cancers in Massachusetts Men – 1982-1996". Some statistics from her presentation follow:

- Between 1982 and 1996, a total of 200,032 men in Massachusetts were diagnosed with new cancers. (This number excludes skin cancers other than melanoma, which are not reportable to the Massachusetts Cancer Registry.) Prostate cancer was the leading type of cancer diagnosed during this period, accounting for 24.3% of all cancers diagnosed in men. In descending order, the next most common cancers diagnosed were lung, colorectal and bladder cancers. Oral and pharyngeal cancer, non-Hodgkin's lymphoma, melanoma and testicular cancer each represented fewer than 5% of new cancer diagnoses.
- Between 1982 and 1996, a total of 101,104 Massachusetts men died of cancer. Lung cancer was
  the leading cause of cancer deaths in men during this period. It was responsible for 30.4% of
  cancer deaths in men, well ahead of colorectal cancer (the second-leading cause of cancer deaths
  in men). Although prostate cancer was the most commonly diagnosed cancer, it ranked third in
  mortality.

#### **Bladder Cancer:**

- Based on national data, the average man has approximately a 3.4% risk of developing invasive bladder cancer over his life, or about one in 30 chance. The risk of bladder cancer is higher in white males (3.7%, or 1 in 27) than in black males (1.2%, or 1 in 85).
- In Massachusetts, 11,415 new cases of bladder cancer were reported in men between 1982 and 1996. During this period, bladder cancer accounted for 5.7% of all newly diagnosed cancers in males. In 1996, 763 men in the state were diagnosed with bladder cancer, for an age-adjusted incidence rate of 23.7 cases per 100,000 men.
- The age-adjusted incidence rate of bladder cancer in Massachusetts men has decreased over time, from 27.6 per 100,000 in 1982 to 23.7 per 100,000 in 1996 a decrease of 14%. During this period the incidence of bladder cancer in SEER areas remained steady at about 30 cases per 100,000 men from 1982 through 1988, and then began a slow decline to 27.7 cases per 100,000 in 1996. The 1996 rate for SEER registries was 17% higher than in Massachusetts.
- Five-year relative survival rates for men with bladder cancer have increased in the past 20 years, from 79.1% of men diagnosed between 1980 and 1982 to 83.1% of men diagnosed between 1989 and 1995. These increases have been seen in both white and black men, although black men continue to have lower survival rates than white men. Regardless of race, men under the age of 65 years at the time of diagnosis have a better survival rate than those aged 65 years or older.

• Based on national data, the average man has approximately a 5.6% lifetime risk of developing invasive colorectal cancer, or about a one in 18 chance. While incidence has declined in recent years in both white and black men, rates continue to be higher in black men.

#### **Colorectal Cancer:**

- In Massachusetts, 29,593 new cases of colorectal cancer were reported in men between 1982 and 1996. Colorectal cancer was the third most common type of cancer in males during this period, accounting for 14.8% of all newly diagnosed cancers. In 1996, 1,906 men in the state were diagnosed with colorectal cancer, for an age-adjusted incidence rate of 58.9 per 100,000.
- Overall, the age-adjusted incidence rate of colorectal cancer in Massachusetts men has gone down in recent years, from 68.6 per 100,000 in 1982 to 58.9 per 100,000 in 1996 a decrease of 14%. This decrease was comparable to that observed in SEER areas (14% between 1982 and 1996, from 59.2 per 100,000 to 51.1 per 100,000). Massachusetts's incidence continues to be higher than SEER incidence however. The incidence of colorectal cancer increases steadily with age, reaching 450 cases per 100,000 in men aged 80 years and older in Massachusetts.
- Five-year relative survival rates for men with colorectal cancer have increased approximately 7% since 1980, to about 61% with comparable increases occurring in both white and black men.
   Despite these increases, white men have higher survival rates than black men for all stages and age categories. In general, survival rates are comparable for older and younger men. Younger black males have a higher survival rate than older black men.
- Colorectal cancer is the second leading cause of cancer deaths in men in Massachusetts, accounting for 12.4% of cancer deaths between 1982 and 1996. (For 1996, however, prostate cancer mortality was slightly higher). During this period, 12,554 Massachusetts men died of colorectal cancer. In 1996, 745 men died, for an age-adjusted mortality rate of 23.0 per 100,000.
- Although colorectal cancer death rates for Massachusetts men are higher than the overall rates for men in the US, this gap has narrowed over time. Since 1982, the age-adjusted mortality rate in Massachusetts's men has declined 27%, from 31.6 per 100,000 in 1982 to 23.0 per 100,000 in 1996. US rates decreased 19% between 1982 and 1996, from 25.2 per 100,000 to 20.5 per 100,000.

#### **Lung Cancer:**

- Based on national data, the average man has approximately an 8% lifetime risk of developing invasive lung cancer, or about a one in 12 chance. It's important to note that these are average risks, based on data from both smokers and non-smokers. A smoker will have a much higher chance of developing lung cancer, and a non-smoker will have a lower risk. For people who smoke two or more packs of cigarettes a day, the risk is 20 times that of a non-smoker.
- In Massachusetts, 35,332 new cases of lung cancer in men were reported between 1982 and 1996. During this period, lung cancer accounted for 17.7% of all newly diagnosed cancers in men. Between 1982 and 1996, lung cancer was the second most common cancer diagnosed in men, after prostate cancer. In 1996, 2,270 men were diagnosed with lung cancer, an age-adjusted

incidence rate of 72.3 per 100,000.

- Overall, male lung cancer incidence rates in Massachusetts are similar to those in SEER areas. The incidence of lung cancer in Massachusetts men has remained fairly steady over time, at about 80 new cases per 100,000 men through 1993, but has shown about a 10% decline between 1993 and 1996. SEER data have also shown a similar small declince in recent years. These decreases in incidence may be due to changes in smoking patterns among American men in recent decades. Lung cancer incidence increases with age, peaking at about 516 cases per 100,000 men aged 70-79 years in Massachusetts, and then declines slightly in those aged 80 and older.
- Lung cancer has the poorest survival rate of the eight cancers included in this report fewer than 13% of men diagnosed with lung cancer survive at least five years after diagnosis. Men diagnosed at a localized stage have about 45% 5-year relative survival rate. Only about 20% of cases are diagnosed early. Most lung cancers are diagnosed at a regional or distant stage, when the cancer has spread beyond the lung. Rates for men presenting with distant disease are particularly low, with only 1.9% surviving at least five years. There has been little improvements in survival rates over time. Persons who smoke two or more packs or cigarettes a day are 15 to 25 times more likely to die of lung cancer than a non-smoker.
- Lung cancer is the leading cause of cancer death in Massachusetts men, accounting for 30% of cancer deaths. Between 1982 and 1996, 30,698 men died of lung cancer in Massachusetts. Mortality rates remained fairly steady during this period, with a high of 72.4 cases per 100,000 males in 1983. In 1996, 2,047 men in Massachusetts died of lung cancer, for an age-adjusted mortality rate of 64.3 per 100,000 men.
- Lung cancer mortality rates have remained fairly constant in men, but small declines have been
  noted in recent years both in Massachusetts and the US. For the period 1990-1996, lung cancer
  mortality was on average about 7% lower among Massachusetts men than nationally.

#### **Melanoma Cancer:**

- Based on national data, the average man has approximately a 1.6% lifetime risk of developing invasive melanoma (about a one in 63 chance). The risk for a white man is about one in 54, while a black man has a much lower risk, about one in 769.
- In Massachusetts, 5,283 new cases of melanoma were reported in males between 1982 and 1996. During this interval, melanoma accounted for 2.6% of newly diagnosed cancers in males. In 1996, 473 Massachusetts men were diagnosed with melanoma, an age-adjusted incidence rate of 14.4 per 100,000.
- The incidence of melanoma in Massachusetts men has increased approximately 71% since 1982, from 8.4% per 100,000 to 14.4 per 100,000 in 1996. Rates have fluctuated somewhat during this period however, because of the relatively small number of men diagnosed each year. State incidence is about 11% lower than SEER area incidence. One key reason for the lower Massachusetts rates may be that SEER collects information from non-hospital reporting sources

(such as pathology laboratories) as well as hospitals, while Massachusetts data for this period were only reported from hospitals. Nationally, incidence has increased about 62% from 10.5% per 100,000 in 1982 to 17.0 per 100,000 in 1996.

- Overall, five-year relative survival for men diagnosed with melanoma is about 85%. Survival for
  white men has increased over time, presumably due to increased early detection (a greater
  proportion of cases being found earlier). The number of cases in black men is too small to draw
  any definitive conclusions.
- Between 1982 and 1996, 1,571 men in Massachusetts died of melanoma. During this period, melanoma accounted for 1.6% of cancer deaths in men. In 1996, 121 men died, for an age-adjusted mortality rate of 3.7 per 100,000. As with incidence, the small numbers of deaths from melanoma result in year-to-year fluctuations in the mortality rate. Over time, however, Massachusetts rates have increased about 12%, from 3.3% per 100,000 males in 1982 to 3.7 per 100,000 in 1996, and are generally higher than US rates. As noted earlier, incidence rates for Massachusetts are likely lower than SEER rates because Massachusetts case reporting was solely hospital-based during this period. Mortality data may thus prevent more accurate representation of melanoma in Massachusetts.

#### **Non-Hodgkins Lymphoma:**

- In Massachusetts, 7,259 new cases of non-Hodgkin's lymphoma were reported in men between 1982 and 1996. The number of cases diagnosed each year has increased steadily during this time period. This increase is due in part to the increased numbers of lymphoma cases associated with HIV infection and AIDS. Non-Hodgkin's lymphoma was the sixth most common type of cancer in males during this period, accounting for 3.6% of all newly diagnosed cancers. In 1996, 633 men in the state were diagnosed with non-Hodgkin's lymphoma, for an age-adjusted incidence rate of 19.2 per 100,000.
- The age-adjusted incidence rate of non-Hodgkin's lymphoma in Massachusetts men has increased over time, from 11.6 per 100,000 in 1982 to 19.2 per 100,000 in 1996 (an increase of 66%). This increase was higher in Massachusetts than in the country as a whole (48% between 1982 and 1995, from 13.0 per 100,000 to 19.2 per 100,000). The incidence of non-Hodgkin's lymphoma increases steadily with age, reaching a peak of 117 cases per 100,000 in men aged 80 years and older in Massachusetts.
- Five-year relative survival rates for men with non-Hodgkin's lymphoma have been affected by the increasing number of these lymphomas that are associated with AIDS. Overall five-year survival rates peaked at 52.6% among men diagnosed between 1983 and 1985, and declined to 46.8% among men diagnosed between 1989 and 1995. Survival rates are substantially lower among black men, however, falling from 47.3% among men diagnosed between 1980 and 1982 to 37.6% among men diagnosed between 1989 and 1995.
- Non-Hodgkin's lymphoma is the fourth leading cause of cancer deaths in men in Massachusetts accounting for 3.6% of cancer deaths between 1982 and 1996. During this period, 3,648

Massachusetts men died of non-Hodgkin's lymphoma. The mortality rate and number of deaths have increased each year during this period. In 1996, 327 men died, for an age-adjusted mortality rate of 10.1 per 100,000.

• Non-Hodgkin's lymphoma death rates for Massachusetts's men are higher than in men nationally. Since 1982, the age-adjusted mortality rate in Massachusetts's men has increased 51%, from 6.7 per 100,000 in 1982 to 10.1 per 100,000 in 1996. SEER rates increased 34% between 1982 and 1996, from 6.4 per 100,000 to 8.6 per 100,000.

# **Oral and Pharyngeal Cancer:**

- Based on national data, the average man has approximately a 1.5% lifetime risk of developing invasive oral cancer, or about a one in 68 chance. These risks are comparable for white and black men. While incidence has declined in recent years in white men, it has increased somewhat in black men. As with lung cancer, it's important to note that these are average risks, based on data from both smokers and non-smokers. A smoker will have a much higher likelihood of developing oral cancer, and a non-smoker will have a lower risk.
- In Massachusetts, 7,592 new cases of oral cancer were reported in men between 1982 and 1996. Oral cancer was the fifth most common type of cancer in males during this period, accounting for 3.8% of all newly diagnosed cancers. In 1996, 486 men in the state were diagnosed with oral cancer, for an age-adjusted incidence rate of 15.7 cases per 100,000 men.
- Overall, the age-adjusted rate of oral cancer in Massachusetts men has decreased slightly over time, from 17.5 per 100,000 in 1982 to 15.7 per 100,000 in 1996 a decrease of 10%. (Rates have been irregular during this time, however, peaking at 18.9 cases per 100,000 in 1986.) This decrease was lower in Massachusetts than in the country as a whole (15% between 1982 and 1996, from 17.4 per 100,000 to 14.8 per 100,000). The incidence of oral and pharyngeal cancer in Massachusetts men is generally higher than in SEER areas.
- Five-year relative survival rates for men with oral cancer have decreased slightly in the past 20 years, from 52% of men diagnosed between 1974 and 1976 to about 50% for men diagnosed between 1989 and 1995. Among black men, however, survival has fallen from 31% to 28% during this period. White men have higher survival rates than black men for all stages and age categories. Older men have slightly better survival rates than younger men, overall and for white males. Younger black males have a higher survival rate than older black men, however. Survival rates are lower for those men diagnosed at a later stage, regardless of race.
- Oral cancer is the sixth leading cause of cancer deaths in men in Massachusetts for 2.2% of cancer deaths between 1982 and 1996. During this period, 2,219 Massachusetts men died of oral cancer. In 1996, 107 men died, for an age-adjusted mortality rate of 3.5 per 100,000.
- Oral cancer death rates for Massachusetts men are higher than in men nationally, but this gap has narrowed over time. Since 1982, the age-adjusted mortality rate in Massachusetts men has decreased 45%, from 6.4 per 100,000 in 1982 to 3.5 per 100,000 in 1996. US rates decreased

28% between 1982 and 1996, from 5.4 per 100,000 to 3.9 per 100,000.

#### **Prostate Cancer:**

- Based on national data, the average man has about a 16% lifetime risk of developing invasive prostate cancer, or about a one in 6 chance.
- In Massachusetts, 48,565 new cases of prostate cancer were reported between 1982 and 1996. The number of cases doubled from about 2,000 per year to over 4,000 per year during this time. Prostate cancer was the most common type of cancer in males during this period, accounting for 24.3% of all newly diagnosed cancers. In 1996, 4,376 men in the state were diagnosed with prostate cancer, for an age-adjusted incidence rate of 142.5 per 100,000.
- The age-adjusted incidence rate of prostate cancer in Massachusetts men has increased sharply over time, from 73.3 per 100,000 in 1982 to a high of 177.7 per 100,000 in 1992 an increase of 142%. The same pattern was seen in SEER data. This sharp increase is attributed primarily to increased screening, particularly the use of the PSA test. Since 1992, incidence rates have declined both in Massachusetts and nationally. In general, the incidence of prostate cancer has been lower in Massachusetts than in SEER areas, although state incidence was slightly higher in 1995 and 1996. The incidence of prostate cancer increases with age, reaching a peak of nearly 1200 cases per 100,000 men aged 70-79 years. It then declines slightly in men aged 80 years and older.
- Five-year relative survival rates for men with prostate cancer have increased approximately 25% since 1980, to about 92%, with similar increases occurring in both white and black men. White men continue to have higher survival rates than black men for all stages and age categories, however. While survival rates do not differ greatly between men who are younger than age 65 and those who are age 65 and older, survival rates are slightly better for black males under age 65 than those who are age 65 and older.
- Prostate cancer was the third leading cause of cancer deaths in men in Massachusetts between 1982 and 1996, accounting for 11.1% of cancer deaths during this time. (In 1996, prostate cancer became the second leading cause of cancer deaths, surpassing colorectal cancer.) Between 1982 and 1996, 11,216 Massachusetts men died of prostate cancer. In 1996, 821 men died, for an ageadjusted mortality rate of 24.3 per 100,000 men.
- Since 1982, the age-adjusted mortality rate in Massachusetts men has increased from 21.4 per 100,000 in 1982 to a peak of 27.7 per 100,000 in 1992 (a 29% increase). Since then, rates have declined slightly, to 24.3 per 100,000 in 1996 (a 14% decrease since 1992). SEER rates followed a similar pattern during this period, increasing from 23.0 per 100,000 in 1982 to a high of 26.7 per 100,000 in 1991, followed by a slight decrease to 24.1 per 100,000 in 1995.
- Despite the increase in incidence rates, mortality rates for prostate cancer have remained constant. The NCI notes that this is likely due to the fact that a lot of these cancers are being detected early, prior to their becoming life-threatening. The increased use of screening is resulting in a large

proportion of prostate cancers being diagnosed at an early stage, when they are most treatable. **Testicular Cancer:** 

- Based on national data, the average man has approximately a 0.3% lifetime risk of developing invasive testicular cancer, or about a one in 286 chance. The risk of testicular cancer is higher in white males than in black males.
- In Massachusetts, 2,586 new cases of testicular cancer were reported in men between 1982 and 1996. During this period, testicular cancer accounted for 1.3% of all newly diagnosed cancers in males. In 1996, 170 men in the state were diagnosed with testicular cancer, for an age-adjusted incidence rate of 4.7 cases per 100,000 men.
- The age-adjusted incidence rate of testicular cancer in Massachusetts men has increased over time, from 4.4 per 100,000 in 1982 to a high of 5.6 per 100,000 in 1994 –an increase of 27%. During this period the incidence of testicular cancer has varied, however, due to the small number of cases diagnosed annually. The same pattern was seen nationally. The incidence of testicular cancer peaks in men in their twenties and thirties, with an incidence rate of 14 cases per 100,000 in men aged 30-39 years, then decreases with age.
- Testicular cancer has one of the highest relative survival rates of any cancer. Currently, more then 95% of men diagnosed with testicular cancer are alive five years later. Nearly 75% of men who are diagnosed with testicular cancer at a distant stage survive their disease for at least five years.
- Testicular cancer accounted for 0.2% of cancer deaths between 1982 and 1996. During this period, 163 Massachusetts men died of testicular cancer. In 1996, 15 men died, for an age-adjusted mortality rate of 0.4 per 100,000.

At the end of the slide presentation, Chairman Koh added, "I think it is important to note that the male lung cancer mortality rates are starting to decline, in contrast to what we see in women. And you did point out that's because of the greater success of men in quitting smoking over the last several decades. That is something that we need to underscore in this report. The fact that colorectal cancer – only a third of it is found localized is something that should spur us to action. This is a cancer where early detection is everything. You pointed out that screening for colorectal cancer can be embarrassing to talk about but we don't want people dying of embarrassment. Our department in collaboration with communities around the state is trying to raise awareness and improve screening, and prevention efforts. Lung, colorectal, and prostate are areas where prevention and/or early detection can save lives."

Dr. Sterne, Council Member, noted a word of caution, "...that the percentage change in incidence data does not necessarily mean the percentage change in the actual occurrence of the illness in the population. That they more accurately reflect the percentage increase in the incidence of detection — they don't necessarily alter mortality or survival. For example, the incidence increase in prostate cancer of 95% is not matched by a corresponding increase in mortality."

## **No Vote/Information Only**

## "HIV SURVEILLANCE UPDATE"

Dr. Jean McGuire, Director of the AIDS Bureau, presented the "HIV Surveillance Update" to the Council. She said in part, "It's been approximately 18 months since you approved the regulations that required the reporting of both prevalent and incident cases during that period of time. We believe that we have achieved not only an excellent profile of individuals that are currently in care in the state but an excellent collaboration with consumers and with providers that really make this a unique and promising system...Dr. Koh initiated an implementation team that includes members from the Mass. Medical Society, clinics and hospitals throughout the State, and consumer advisory boards so that we have a multi-level process that has really assured a great deal of confidence in the reporting that we received and in the data. Consumers walk in and hand the reporting forms to their doctors or nurses and say 'please make sure that I've been reported,' because of their confidence in the privacy and confidentiality of our non-name-based system.

Dr. Alfred DeMaria, Assistant Commissioner, Bureau of Communicable Disease Control, added "I think the major message today is that this system has been a success, thanks to the participatory process....It turned out extremely well both in terms of the data and the effectiveness in the community with people using the system, and I'm happy to say with a major change in the attitude of colleagues at the CDC, in terms of whether this is possible to do or not. It's been a success and I think the measure of that will be seen in Andrew's presentation."

Mr. Andrew Fullem, Director, AIDS Surveillance, provided a slide presentation on the HIV epidemic in the state of Massachusetts. He said in part, "... As of the end of February, we had 6,515 people living in the state of Massachusetts who have had an AIDS diagnosis....The general findings from the system have been that it has been a tremendous success. We have had a high level of both provider reporting, and cooperation from laboratories, which has really been a voluntary part of this reporting system, and they have been not required by regulation to participate. The completeness of the coded elements has been very high, and actually much higher than we expected, which gives us great confidence in the ability of the code to identify individuals while continuing to protect their confidentiality. This data adds a new dimension and a richer and more complex understanding of the epidemic in the state of Massachusetts and that there are distinct HIV epidemics across the state. We received responses from 157 institutions in this first year of reporting from licensed medical providers and facilities in the state. Fourteen sites reported having 100 or more HIV positive people in care. Five sites reported having between 75 and 99, and 8 between 50 and 74. We have 114 providers who reported in the state having fewer than 25 people in care. They may have as few as 1 case or as many as 24. There seems to be a number of providers in the state that have a relatively small number of people in care. That creates a challenge for us as well. When we look at what the providers have been reporting, we received 6,091 cases that came in, initially indicated as being folks who are HIV positive without an AIDS diagnosis. Sixty-seven of those people were not Massachusetts residents, based on the zip code that was in the coded identifier, so they are not included in the analysis. We have 422 people who had been previously reported. The duplicate information is added to the AIDS registry, and they are not included in the

discussions of HIV cases. We have 163 people who should have been reported as AIDS cases. We had 38 people in this first year that progressed from AIDS. They physically progress out of the HIV database into the AIDs database. We have 14 people who died without an AIDS diagnosis. They are not included in the final number. We have 569 people who were reported duplicately from a number of different institutions. That leaves us with 4,818 initial cases reported in this first year. I just want to remind folks that we have 6,515 people living with AIDS...."

In summation, Mr. Fullem noted, "The HIV/AIDS epidemic in Massachusetts is complex, and widely different as we look at different health service regions across the state. Injecting drug use remains the predominant mode of exposure to HIV in the state. But men who have sex with men is a significant part of the epidemic, particularly when we look at Boston, the metro West, and the Southeast regions of the state. Women are an increasing proportion of the population living with HIV and AIDS. In the Western part of the state and the Springfield area, 45% of those people living with HIV are women. The communities of color continue to represent a significant proportion of people living with HIV. A significant proportion of people living with an HIV diagnosis received their initial diagnosis and went into medical care in their twenties."

Dr. McGuire concluded, "We have been waiting for a number of years to have a profile of the epidemic that more readily indicated what the leading edge of the disease is, where we need to put our resources. We have many planning groups around the state, 20 local care consortia that organize the clinical and social support. We have a prevention-planning group that designs and allocates resources for prevention. And we have a consumer advisory board that reviews our ongoing allocation and program planning efforts. We consider this to be a very important tool, particularly as we continue to move forward in looking at the very localized experiences of the epidemic. It confirms much of what we already know, because in this state, we have the good fortune to have a lot of resources both in prevention and care. But it provides a clarity around the data, and around the impact, and the differentials that will allow for improved program planning in the future."

Dr. Koh, Chairman, stated, "To put this into context for everybody, the challenge has been: can we track this epidemic more accurately: quantifying the HIV positive population in the state, as well as the AIDS population; and do this in a way that protects confidentiality using a non-name unique identifier? And the answer today is yes. This is a national model. The CDC has paid a lot of attention to this. I think there are a lot of people in the room who should feel very proud of their contributions to this really very successful tracking method. I think the other key message that comes out of this is there's been a little less attention paid to HIV/AIDS recently because deaths are dropping. But this is still a devastating illness. I often point out that this has gone from an acute devastating illness to a chronic devastating illness. And I think some of the numbers that you presented today support that."

#### **No Vote/Information Only**

#### **REGULATIONS:**

# REQUEST FOR FINAL PROMULGATION OF AMENDMENT TO 105 CMR 590.000 OF THE STATE SANITARY CODE – CHAPTER X – MINIMUM STANDARDS FOR FOOD ESTABLISHMENTS:

Ms. Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management, presented to the Council, the request for final promulgation of Amendment to 105 CMR 590.000 of the State Sanitary Code accompanied by Ms. Priscilla Neves, Food Protection Supervisor, Division of Food and Drugs and Attorney Tracy Miller, Deputy General Counsel, Office of the General Counsel. Ms. Ridley said, "...Back in October we came before you with our proposal to rewrite our food establishment regulations for the first time in over ten years. At that time and we still are proposing to adopt by reference the federal national model that is collaboratively adopted by all 50 states. Every two years there is a meeting where we review all the components of the model food code, and come up with a nationally-based, science-based code that really puts a lot of emphasis on critical control points in both retail food, and food service establishments. In addition to adopting the federal code, we have added in Massachusetts what we call the State Supplemental Code and we have included a Food Code Comparison Guide which tells you which items in the code come from either the State Supplemental Code or the Federal Model Code. These will all be available as a package at the State House Book Store. We held a series of public hearings in Jamaica Plain (November 16, 1999), Hyannis (November 8, 1999) and Westfield (November 15, 1999) and received a number of comments back on the code...Some of the more significant provisions included time and temperature requirements that have become important and critical in our understanding of preventing food-borne illness, particularly with such emerging pathogens as the e.coli 0157:H7 strains, the listeria strains, and a number of other organisms that have become more recently recognized as real causative factors. One of the major changes in addition to time and temperature is for the first time a requirement that food managers are going to have to be both trained and certified in accordance with programs that are approved according to standards and guidelines that are set by the Department of Public Health. There is a phase-in to allow this to happen over the next year. Another change is a mandatory requirement for consumer advisories to warn or advise consumers about products that are on the menu or that are being sold that are either raw or undercooked, particularly in terms of susceptible populations. Originally, we intended to have the code go into effect on July 1 but we have extended that date to October 1 because as soon as we completed the code, we had five training sessions and they were immediately filled. We are facing an unprecedented demand for additional training for local boards of health and the industry itself, which will take us through the summer to accommodate. The other component that will be delayed is the consumer advisory, which is controversial nationally and not many states have adopted it for all menus and retail stores. We are leaving it in with an effective date of January 1. There will be a Federal Food Conference in the next month in which we expect to receive additional resolution and direction on how to advise consumers. There is one other point which was quite controversial and that is bare hand contact of ready-to-eat foods. We prohibit most bare hand contact of ready- to-eat foods. But one of the key points is we advised against the use of any latex single-use gloves. There are alternative, very acceptable, equally priced gloves available that do not pose the hazards that single-use latex gloves do to many individuals, both occupationally and as consumers."

Ms. Priscilla Neves, Food Protection Supervisor, Division of Food & Drugs added, "The bare hand contact has been very important and what we have found out is that complete restriction of not touching ready-to-eat, potentially hazardous foods is almost impossible. We have come up with an alternative procedure for bare hand contact which requires additional active managerial control, a written procedure that you can demonstrate that you have trained your employees and that you have adequate hand washing facilities and that you have indicated how you plan on monitoring your employees. We have met with a new organization called the New England Mobile Food Service Association (i.e., canteen trucks) received a lot of information, modified the regulations, and everybody is very happy. We have a new channel of communication with a group that has been on the high end of violations."

Ms. Ridley noted that the code is written by the state but is enforced by the 351 cities and towns by their local Boards of Health which do the inspections. She said further that the requirements for certified food managers is also going to extend to the Boards of Health. Therefore if you are not a Certified Health Officer, CHO, or an RS, Registered Sanitarian, you are going to have to demonstrate the same level of knowledge by attending an approved training program as a certified food manager to create a level playing field. In conclusion staff noted that the local Boards of Health, as well as the food industry, welcome the implementation of these revised regulations.

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve the **Final Promulgation of Amendment to 105 CMR 590.000 of the State Sanitary Code** – **Chapter X** – **Minimum Standards for Food Establishments**; that a copy be attached and made a part of this record as **Exhibit Number 14,672**; and that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth for promulgation.

Examples of significant provisions of the Food Code and the 105 CMR 590.000 Supplement include:

- Detailed charts giving specific guidance for time, temperature and humidity for cooking meat and other raw foods derived from animals.
- Modification of time and temperature controls for cooking hamburgers and pork, as well as criteria for types of beef that can be served rare without a consumer advisory.
- Recommendations to food establishment managers on how to ensure food workers' health and hygiene practices including provisions that prohibit bare-hand contact with ready-to-eat foods.
- Mandatory demonstration of knowledge requirements for managers in the prevention of food-borne illness.
- Provisions for using time as a public health control.
- Safe handling instructions for retail operations that package meat and poultry products.

- Modification of recommendations related to reduced oxygen packaging to more clearly address Clostridium botulinum as a potential hazard in certain packaging processes.
- Consumer Advisories to warn consumers that certain foods should be ordered and eaten fully cooked in order to ensure their safety.
- Enhanced food safety protection for highly susceptible populations from the potential risks associated with raw shellfish, eggs, juices and raw seed sprouts.
- Specific food safety requirements for mobile food units, residential kitchens and bed and breakfast establishments.
- Changes in administrative and enforcement processes.

Major changes to 105 CMR 590.000 pursuant to public comments include:

- The effective date of the regulations will be October 1, 2000. The date has been moved upto allow for additional training programs and so that major changes may be implemented.
- The regulations will outline the circumstances for assigning an alternate "person in charge" and the responsibilities of an alternate person in charge.
- Only diseases transmissible by food will be included in the list of diseases reportable to the Bureau of Communicable Disease.
- The definition of E.coli 0157:H7 will be expanded to include all strains of Enterohemmorraghic Eschericia coli (EHEC).
- Requirements for bare-hand contact with ready-to-eat foods will be clarified.
- Labeling regulations regarding ingredient statements will be clarified.
- Mobile food operations will be permitted to serve bulk potentially hazardous foods provided that the operators meet certain requirements.
- The Department will continue to allow the retail sale of certain limited non-PHF food products prepared in residential kitchens that meet the requirements specified in these regulations. The Department will in the near future be developing specific requirements for the wholesale of certain products from residential kitchens under the Department's Food Processing regulation, 105 CMR 500.000.

- Requirements for a consumer advisory regarding the risks of eating raw or under-cooked animal foods will remain in the regulations and will be implemented on January 1, 200l.
- The Administration and Enforcement section of the code will describe when hearings before the local Boards of Health are mandated.

# REQUEST FOR EMERGENCY PROMULGATION OF AMENDMENTS TO THE SUITABILITY REVIEW PROCESS HSA V PILOT PROJECT – 105 CMR 153.022 (B):

Dr. Paul Dreyer, Director, Division of Health Care Quality, presented the request for emergency promulgation of regulations 105 CMR 153.022 (B). He said in part, "... This is a request for emergency promulgation of amendments to the suitability review process in HSA V. The current regulation expires on March 31 – that is why we need to promulgate these on an emergency basis so that there is no time lapse. These regulations essentially extend the current pilot project in HSA V another five years through 2005. These regulations afford an opportunity for people in this geographic area to comment on proposed transfers of ownership of long term care facilities. It is a process whereby people may request a public hearing, following a notice in the newspaper. Since 1990 there have been 60 public notices of intent to acquire long term care facilities in HSA V, which is Southeastern Massachusetts, and there have been 23 public hearings. We held a public hearing and a comment period on these regulations and heard comments from Cape United Elderly which recommended that the pilot project go statewide. There were several other comments that supported that proposal. We heard from the Massachusetts Extended Care Federation, which supported the extension of the pilot project on HSA V for the five years but opposed any statewide expansion. They argued there were sufficient safeguards to protect the public from unsuitable providers in the current process. We believe that the process has not given us a lot of new information about applicants and so hasn't assisted us in doing a suitability review. What it has done is afforded the people in the Cape an opportunity to meet and interact with the proposed new owners. We have not heard from any community groups elsewhere in the state that are interested in such a process. We believe that the most sensible course is to go forward another five years in HSA V."

Council Member Sterne asked whether the marketing or eliciting of responses is the reason why we haven't heard any response from the rest of the state. Dr. Dreyer replied that he isn't aware of any well organized community groups like in the Cape elsewhere in the state.

After consideration, upon motion made and duly seconded, it was voted (unanimously): That the **Request for Emergency Promulgation of Amendment to the Suitability Review Process HSA V Pilot Project – 105 CMR 153.022 (B)** be approved; that a copy of the emergency regulations be attached and made a part of this record as **Exhibit Number 14,673**; and that a copy of the emergency regulations be forwarded to the Secretary of the Commonwealth.

# REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO LONG TERM CARE FACILITY LICENSURE REGULATIONS:

Dr. Paul Dreyer, Director, Division of Health Care Quality, made introductory remarks, stating that over the years, during bad heat waves over the summer, people in nursing homes become dehydrated and end up in acute care hospitals. Last summer elderly patients died due to the heat. "We decided it was time to more aggressively see what we could do to resolve this problem by requiring air conditioning in long term care facilities", he said.

Ms. Jean Pontikas, Assistant Director, Division of Health Care Quality, presented the regulations to the Council. She said, "...We are here to request final promulgation of amendments to 105 CMR 150.000 Licensing of Long Term Care Facilities and to 105 CMR 151.000 The General Standards of Construction for Long Term Care Facilities. These requirements will establish standards that long term care facilities provide air conditioning in common spaces within the licensed nursing and rest homes. At its August 17, 1999 meeting, the Public Health Council released for public comment proposed amendments which would require that all long term care facilities provide air conditioning in dining rooms, activity rooms, nursing units, nursing unit corridors, and other common areas sufficient to maintain a temperature of 75 degrees in those areas during the summer months. And the facilities were to come into compliance with this standard by June 1, 2000. The proposed regulations also required that newly constructed facilities or facilities undergoing major renovations include air conditioning systems throughout the newly constructed or the renovated areas. The current long term care regulations are silent on this issue, as are the federal requirements. We did a survey of nursing and rest home facilities last summer which indicated that at that time, 90 percent of nursing homes were providing some air conditioning in common areas, and 50 percent of the rest homes provided air conditioning in common areas. There was also a subgroup that was providing air conditioning in the resident rooms, and another subgroup that had central air conditioning, and we think that's about 130 of the 580 facilities. We also found that the newly constructed facilities (within the last 10 years) had all been built with central air conditioning in all of the core and the patient areas. With the experience of the heat waves last summer...it led us to really take another look at this issue that has been coming up every year to see whether or not we should propose something that might be of benefit to the health and safety of the residents of the facilities. We held a public hearing on January 13. It snowed that day, and approximately five people attended the hearing. Four people provided oral testimony. We also received written testimony from eight individuals or groups. The summary of the comments is attached to your memorandum. All of the comments concerning the new construction requirements or renovated areas were positive and in support of the regulations. Nine individuals/groups agreed that there was need to provide air conditioning and access to cooled common areas during the summer months for the residents of the facilities. However, they did have specific concerns about the details within the proposed regulation." The concerns are:

(1) The cost of installing air conditioning in older existing facilities – in particular, the requirement that nursing unit corridors be air-conditioned:

The commenters pointed out that there are many different design layouts, and that it would be especially difficult for rest homes in older facilities to undertake the extensive renovations that would be necessary to achieve compliance with the standard. The cost of electrical wiring and duct work to install the air conditioning in corridors would be extraordinary; and the range of estimates mentioned in the comments was between \$11,000 and \$1,000,000, depending on the size, the physical layout, and the electrical capacity of the facilities.

The testimony presented has convinced the Department that requiring air conditioning in the nursing unit corridors would be of little benefit to residents and would be cost prohibitive for many older facilities. Therefore, the requirement to air condition nursing unit corridors has been eliminated from the proposed regulations. The regulations require that facilities provide air conditioning in dining rooms, activity rooms, day rooms, solariums, sitting rooms or equivalent common areas. We believe this change both ensures cooled areas during the summer and it eliminates many of the concerns about costs of implementing air conditioning requirements. In many instances, facilities will be able to comply with the regulation by installing window air conditioning units.

# (2) Maintaining a 75 degree temperature at all times:

The regulation specified to maintain a maximum temperature of 75 degrees at all times during the summer. This was interpreted by many individuals to mean that we were requiring that they maintain that temperature at a constant level during the summer months. The commenters felt that this would be too cold for the residents of the facility. The owners of the facilities feel they have the experience and know their residents prefer warmer temperatures, whether it be summer or winter.

It was never the Department's intent to require the facilities to maintain that temperature. Instead, the Department wanted the facilities to have an air conditioning system that's <u>capable</u> of maintaining a 75 degree temperature during the summer months. As a result of these comments, the Department made changes to the regulations requiring that they **have a system capable of maintaining a maximum temperature of 75 degrees Fahrenheit.** In addition, we have added a new sentence requiring that the facility **maintain a temperature that is at a level which ensures the comfort and the health of the residents of the facility.** 

## (3) Proposed Implementation Date of June 1, 2000:

Staff agreed that a June 1, 2000 compliance date would have been difficult for facilities to meet if the requirements to air condition nursing unit corridors remained in the regulations. However, the change to not require air conditioning of nursing unit corridors eliminates most of the concerns about the costs of implementation because it greatly reduces the likelihood that facilities will have to undertake extensive cost prohibitive renovations to meet the new standard. Many facilities will be able to comply with the new proposed regulations by installing window air conditioning units. In recognition of the fact that there have been delays in bringing this regulation forward for final promulgation, we have **extended the compliance deadline to June 21, 2000, coinciding with the beginning of the summer season.** 

In conclusion, Ms. Pontikas said, "We have taken a look at this and the effect of not having air conditioning on the residents in the facility. We believe that it is very important for the residents' health and safety. In a study conducted last summer, 4% of the facilities reported heat-related problems for residents of the facility. We think that this has a very direct benefit for the residents of the facility and are recommending that the Public Health Council promulgate the amendments to 105 CMR 150.000 and 105 CMR 151.000."

Chairman Koh, added, "Just to put this into perspective. I think everybody remembers last summer when we had that intense statewide concern about several deaths in nursing homes in the midst of an extraordinary heat wave. Questions were raised were we doing everything possible to ensure the health and safety of some of the most vulnerable people in our state. This is the end result. It think it's a reasonable one, and one that would continue to protect people in nursing homes, provide air conditioning in common places in older facilities, as you pointed out and make it mandatory throughout for new facilities. I would urge the Council to accept this...."

Council Member Dr. Sterne made some comments. One of his comments was a concern that "most immobile (i.e., bed or chair patients) are the ones that are most prone to temperature-related illness and are least able to auto-regulate their core temperatures. These are also the people who do not access the common spaces that exist in nursing home facilities...I'm concerned about the absence of regulation input regarding the spaces where the most infirm folks live. They take their meals in bed etc.".... In response to this comment, Dr. Dreyer said that during heat waves, immobile patients are assisted by facility staff and moved into cooler spaces. What these regulations will do is make more space available to accommodate those patients. Ms. Pontikas also responded to Dr. Sterne's question by stating that approximately 50% of facilities provide some air conditioning in resident rooms to accommodate the needs of patients who are unable to move to the activity and dining areas.

After consideration, upon motion made and duly seconded, it was voted (unanimously): That the Request for Final Promulgation of Amendments to Long Term Care Facility Licensure Regulations 105 CMR 150.000 and General Standards of Construction 105 CMR 151.000 Governing the Provision of Air Conditioning be approved; that a copy be attached and made a part of this record as Exhibit Number 14,674; and that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth for promulgation.

# **DETERMINATION OF NEED PROGRAM:**

# CATEGORY 1 APPLICATION: PROJECT APPLICATION NO. 2-3976 OF UMASS MEMORIAL MEDICAL CENTER, INC.:

Ms. Joyce Jame, Director, Determination of Need Program, introduced Ms. Holly Phelps, Consulting Analyst for the project 2-3976. Ms. Holly Phelps said, "...The Umass Memorial Medical Center (UMMMC) is proposing to establish an Extracorporeal Membrane Oxygenation Service (ECMO). Extracorporeal Membrane Oxygenation is a cardiac bypass technique used with severe

cardiopulmonary failure. It was originally developed for use with neonates, but now it is used with children and adult populations as well. The procedure involves taking blood from a vein in the neck, through a tube taking it through the oxygenator, which functions as an artificial lung. Then through a heat exchanger that maintains it at body temperature, and then puts it back through an artery in the neck. The recommended maximum capital expenditure for the project is \$91,630. And the estimated operating cost per patient is \$33,816. In addition, Umass Memorial Medical Center is the successor corporation to Umass Medical Center, and is therefore bound by the conditions on Umass's liver transplant DoN approval, which required Umass to have an ECMO service prior to initiating any pediatric liver transplantation. Thus, this application is required for compliance with that condition."

After consideration, upon motion made and duly seconded, it was voted (unanimously): to approve **Project Application #2-3976 of Umass Memorial Medical Center, Inc.,** based on staff findings, with a maximum capital expenditure of \$91,630 (August 1999 dollars) and first year incremental operating costs of \$33,816 (August 1999 dollars). A copy of the staff summary is attached and made a part of this record as **Exhibit No. 14,675**. As approved, the application provides for the establishment of an Extracorporeal Membrane Oxygenation Service. This Determination is subject to the following conditions:

- (1) The applicant shall accept the maximum capital expenditure of \$91,630 (August 1999 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 752.
- (2) The applicant shall contribute 100% in equity to the final approved maximum capital expenditure.
- (3) The applicant shall contribute \$75,000 (\$15,000 per annum for five years) to pay a portion of the salary of the Program Coordinator for the Next Step Program. This program is an educational collaborative of the Worcester Latino Coalition, UMass Medical School and local colleges which assists minority paraprofessionals working in health care organizations to achieve higher educational degrees.

Staff's recommendation was based on the following findings:

- (1) UMMMC is proposing to establish an ECMO service.
- (2) The health planning process for this project was satisfactory.
- (3) The proposed project complies with condition number two (2) of approved DoN No.2-3937 which requires UMMMC to establish an ECMO service prior to performing pediatric liver transplantations.
- (4) The project meets the operational objectives factor of the DoN regulations.

- (5) The project meets the standards compliance factor of the DoN regulations with a condition.
- (6) The recommended maximum capital expenditure is reasonable compared to similar, previously approved projects.
- (7) The recommended incremental operating costs are reasonable based on the scope of the project.
- (8) The project is financially feasible and within the financial capability of the applicant.
- (9) The project meets the relative merit requirements of the DoN regulations.
- (10) The proposed community health service initiatives are consistent with DoN regulations with a condition.

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The meeting adjourned at 11:50 A.M.

Howard K. Koh, M.D., M.P.H. Chairman

LMH/lmh